Alexion Reports Third Quarter 2010 Results

- Strong initial launch of Soliris(R) in Japan -
- Steady addition of new patients on Soliris in U.S. and Europe -
- Guidance raised for 2010 revenues and non-GAAP EPS -
- Positive interim data from current studies of eculizumab in patients with aHUS -

Third Quarter 2010 -- Selected Highlights:

Financial:

- **Soliris(R) (eculizumab) net product sales increased 38 percent to $141.6 million in Q3 2010, compared to $102.6 million in Q3 2009.**
- **Q3 GAAP net income increased to $27.9 million, or $0.30 per share, compared to GAAP net income of $26.7 million, or $0.29 per share, in Q3 2009. (Q3 2009 GAAP net income benefited from a tax rate of 3.4 percent, since it was prior to the Company's Q4 2009 valuation allowance reversal.)**
- **Q3 non-GAAP net income increased 40 percent to $47.2 million, or $0.50 per share, compared to non-GAAP net income of $33.7 million, or $0.37 per share, in Q3 2009.**

Clinical Development:

- **Interim results from Phase 2 studies of eculizumab in patients with atypical Hemolytic Uremic Syndrome (aHUS) published in ASN abstracts**
- **Study of eculizumab in children with aHUS commenced**
- **Transplant programs progress**

CHESHIRE, Conn., Oct 21, 2010 (BUSINESS WIRE) -- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today announced financial results for the three and nine months ended September 30, 2010.

Third Quarter 2010 Financial Results:

For the three months ended September 30, 2010, Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company") reported total revenues of $141.6 million from net product sales of Soliris(R) (eculizumab), compared to $102.6 million in Q3 2009, reflecting the strong addition of new patients in the U.S. and in European countries, and the initial launch of Soliris in Japan, during the quarter.

Soliris is the only treatment specifically indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), an ultra-rare, debilitating and life-threatening blood disorder. Soliris was approved by the U.S. Food and Drug Administration and the European Commission in 2007 and by Japan's Ministry of Health, Labour and Welfare in 2010.

Alexion's non-GAAP operating results are equal to its GAAP operating results adjusted for only share-based compensation and non-cash tax expense. Non-cash tax expense represents the reduction in cash taxes attributable to the utilization of U.S. net operating losses. The following summary table is provided for investors' convenience.

(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Total revenues	$ 141,569	$ 102,628	$ 384,982	$ 276,151
GAAP net income	$ 27,873	$ 26,731	$ 70,580	$ 58,039
Share-based compensation	8,379	6,979	24,733	21,853

Non-cash tax expense	10,931	-	23,369	-
Non-GAAP net income	$ 47,183	$ 33,710	$ 118,682	$ 79,892
Shares used in computing diluted earnings per share (GAAP)	93,021	90,946	92,580	90,246
Shares used in computing diluted earnings per share (non-GAAP)	94,217	92,143	93,823	91,488
GAAP earnings per share - diluted	$ 0.30	$ 0.29	$ 0.76	$ 0.65
Non-GAAP earnings per share - diluted	$ 0.50	$ 0.37	$ 1.27	$ 0.88

Third Quarter 2010 Non-GAAP Financial Results:

The Company reported non-GAAP net income for Q3 2010 of $47.2 million, or $0.50 per share, an increase of 40 percent compared to $33.7 million, or $0.37 per share, in Q3 2009.

Alexion's non-GAAP operating expenses for Q3 2010 were $74.3 million, compared to $55.9 million for Q3 2009. Non-GAAP research and development (R&D) expenses for Q3 2010 were $23.1 million, compared to $19.2 million for Q3 2009. The increase in R&D expenses primarily reflected the Company's expanded clinical development programs. Non-GAAP selling, general and administrative (SG&A) expenses for Q3 2010 were $51.1 million, compared to $36.7 million for Q3 2009. The increase in SG&A expenses primarily reflected costs associated with the expansion of the Company's worldwide operations.

Third Quarter 2010 GAAP Financial Results:

The Company reported GAAP net income for Q3 2010 of $27.9 million, or $0.30 per share, compared to $26.7 million, or $0.29 per share, in Q3 2009. Q3 2009 GAAP net income benefited from a tax rate of 3.4 percent, since it was prior to the reversal of the valuation allowance on U.S. deferred tax assets. Alexion's GAAP operating expenses for Q3 2010 were $82.4 million, compared to $62.8 million for Q3 2009. GAAP R&D expenses for Q3 2010 were $25.2 million, compared to $21.3 million for Q3 2009. GAAP SG&A expenses were $57.2 million for Q3 2010, compared to $41.5 million for Q3 2009.

As of September 30, 2010, the Company had $298.6 million in cash, cash equivalents and marketable securities, compared to $248.8 million at June 30, 2010.

"We are pleased with the continued growing strength of our global operations in the third quarter, highlighted by the success of the initial launch of Soliris for patients with PNH in Japan," said Leonard Bell, M.D., Chief Executive Officer. "Further, we are encouraged by the positive interim data from our two studies of eculizumab in patients with aHUS and look forward to advancing this important program."

2010 Financial Guidance:

The Company is raising its 2010 financial guidance for revenues and non-GAAP earnings per share (EPS). Guidance for 2010 worldwide net product sales has been raised from the previously provided range of $515 to $530 million to the higher range of $536 to $538 million. Guidance for 2010 non-GAAP EPS has been raised from the previous range of $1.63 to $1.68 to the higher range of $1.73 to $1.75, based on a forecast of approximately 94 million fully diluted shares outstanding for 2010.

Guidance for 2010 non-GAAP operating expenses is being narrowed within the upper end of the previously provided guidance range, now to $290 to $295 million. Within this 2010 non-GAAP operating expense guidance, R&D expense guidance has been lowered from the previous range of $95 to $100 million to the lower range of $92 to $94 million, while 2010 guidance for non-GAAP SG&A expenses has been raised from the previous range of $190 to $195 million to the higher range of $198 to $201 million. The increase in non-GAAP SG&A expense guidance relates primarily to accelerated investment in the Company's nephrology therapeutic area and the earlier than expected launch of Soliris in Japan. The Company is raising its guidance for its 2010 GAAP tax rate from a previous range of 30 to 32 percent to the higher range of 32 to 33 percent. The Company is lowering its guidance for its 2010 non-GAAP tax rate, which excludes non-cash tax expense, from a previous range of 11 to 12 percent to the lower range of 9 to 11 percent.

The Company is reiterating other elements of its 2010 fiscal year guidance. Cost of sales is anticipated to be in the range of 12 to 13 percent, and share-based compensation expense for the year is expected to be in a range of $32 to $34 million.

Third Quarter 2010 Research and Development Progress:

During the third quarter, Alexion made continued progress on advancing the development of Soliris as a treatment for patients suffering from ultra-rare and severe complement-mediated disorders beyond PNH, with a focus on its two lead nephrology programs: aHUS and transplant.

Atypical Hemolytic Uremic Syndrome (aHUS)

Interim Data from Current Studies

Alexion has announced that, in interim analyses, its two open-label Phase 2 studies investigating eculizumab as a treatment for patients with atypical Hemolytic Uremic Syndrome (aHUS) have met the primary and key secondary endpoints with high clinical and statistical significance.

These two clinical studies investigate eculizumab for the treatment of patients with aHUS who (i) were resistant or intolerant to plasma therapy, or (ii) were receiving plasma therapy chronically. The studies include adolescent and adult patients and are ongoing. In both studies, interim results were reported at the last captured time point. Eculizumab appeared to be well-tolerated in the studies, with the most common adverse events including anemia, diarrhea, headache, nausea and hypertension.

aHUS is an ultra-rare, chronic and life-threatening disease in which uncontrolled complement activation causes blood clots in small blood vessels (thrombotic microangiopathy, or TMA) throughout the body leading to stroke, heart attack, kidney failure and death.[1,2] Approximately 60 percent of patients with aHUS require dialysis, a kidney transplant, or die within a year of diagnosis.[2] Abstracts summarizing these interim data have been posted on the web site of the American Society of Nephrology (ASN) at http://www.abstracts2view.com/asn/. These two trials are currently ongoing, and data are expected to be presented at the ASN annual meeting held November 18 to 21 in Denver, Colorado.

Pediatric Study

Alexion has commenced a Phase 2, open-label, single-arm, multi-center study of eculizumab in pediatric patients with aHUS in the United States, European Union and Canada. Information about the trial is posted on www.clinicaltrials.gov, Identifier Number NCT01193348. Physicians and families who are interested in participating in this clinical trial can learn more by contacting Alexion by e-mail at clinicaltrials@alxn.com, or by visiting the Alexion website at www.alexionpharma.com and clicking on the clinical trials link.

Transplant: Acute Humoral Rejection (AHR)

Eculizumab is being investigated as a treatment for patients undergoing kidney transplant who are at elevated risk of antibody mediated rejection, also known as acute humoral rejection, or AHR. The Company is supporting investigator-initiated studies in elevated-risk kidney transplantation in the U.S. and Australia. Separately, an investigator-initiated study in patients with ABO blood-type incompatibility is enrolling. Alexion is now planning a single, global, company-sponsored controlled clinical trial using eculizumab to prevent AHR in patients undergoing kidney transplant. The global study is expected to commence in multiple centers next year following protocol finalization.

Oncology Program: Samalizumab

As previously announced, Alexion has completed enrollment in its Phase I single dose, dose-escalation clinical study of samalizumab, its anti-CD200 antibody, in patients with treatment refractory chronic lymphocytic leukemia or multiple myeloma. The trial has enrolled 26 patients. Several patients in the trial have elected to receive multiple doses of samalizumab in an extension of the original trial. A further presentation of data from this study is expected before the end of the year.

Conference Call/Web Cast Information

Alexion will host a conference call/webcast to discuss matters mentioned in this release. The call is scheduled for today, October 21, at 10:00 a.m., Eastern Time. To participate in this call, dial 719-457-2631, confirmation code 3490595, shortly before 10:00 a.m., Eastern Time. A replay of the call will be available for a limited period following the call, beginning at 2:00 p.m., Eastern Time. The replay number is 719-457-0820, confirmation code 3490595. The audio webcast can be accessed at www.alexionpharma.com.

About Soliris

Soliris is a first-in-class terminal complement inhibitor developed from the laboratory through regulatory approval and commercialization by Alexion. Soliris has been approved in the U.S., European Union, Japan and other territories as the first treatment for patients with PNH, an ultra-rare, debilitating and life-threatening blood disorder defined by uncontrolled complement activation which causes chronic hemolysis, or the destruction of red blood cells. Prior to these approvals, there were no therapies specifically available for the treatment of patients with PNH. Eculizumab (Soliris) is not approved for the treatment of aHUS, transplant or other indications other than PNH. Alexion's innovative approach to complement inhibition has received some of the pharmaceutical industry's highest honors: the 2008 Prix Galien USA Award for Best Biotechnology Product with broad implications for future biomedical research and the 2009 Prix Galien France Award in the category of Drugs for Rare Diseases. More information on Soliris is available at www.soliris.net.

About Alexion

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company working to develop and deliver life-changing treatments for patients with serious and life-threatening medical conditions. Alexion is engaged in the discovery, development and commercialization of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic and kidney diseases, transplant, other inflammatory disorders, and cancer. Soliris is Alexion's first marketed product, and the Company is pursuing potential new indications for Soliris beyond PNH, as well as early-stage development of other antibody product candidates. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at www.alexionpharma.com.

This press release includes certain non-GAAP financial amounts that are adjusted from GAAP amounts. Alexion believes that these non-GAAP financial amounts, when considered together with the GAAP amounts, can enhance an overall understanding of Alexion's past financial performance and its prospects for the future. The non-GAAP financial amounts are included with the intent of providing both management and investors with a more complete understanding of underlying operational results and trends. In addition, these non-GAAP financial amounts are among the primary indicators Alexion management uses for planning and forecasting purposes and for measuring the Company's performance.

These non-GAAP financial amounts are not intended to be considered in isolation or as a substitute for GAAP amounts. A reconciliation of GAAP to non-GAAP amounts is included in this press release.

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This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2010, projected tax rates, assessment of the Company's financial position and commercialization efforts, including with respect to the commercial launch of Soliris in Japan, potential benefits and commercial potential for Soliris, potential of Alexion's complement-inhibition technology for treatment of diseases other than PNH; plans for clinical programs for Soliris in aHUS and other non-PNH indications and for samalizumab; and progress in developing commercial infrastructure. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including for example, decisions of regulatory authorities regarding marketing approval or material limitations on the marketing of Soliris, delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure, delays in developing or adverse changes in commercial relationships, the possibility that results of clinical trials are not predictive of safety and efficacy results of Soliris in broader patient populations, the possibility that initial results of commercialization are not predictive of future rates of adoption of Soliris, the risk that third parties will not agree to license any necessary intellectual property to Alexion on reasonable terms or at all, the risk that third party payors (including governmental agencies) will not reimburse for the use of Soliris at acceptable rates or at all, the risk that estimates regarding the number of patients with PNH or other disorders is inaccurate, and a variety of other risks set forth from time to time in Alexion's filings with the Securities and Exchange Commission, including but not limited to the risks discussed in Alexion's Quarterly Report on Form 10-Q for the period ended June 30, 2010 and in Alexion's other filings with the Securities and Exchange Commission. Alexion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when duty arises under law.

References

(1) Hosler GA, Cusumano AM, Hutchins GM. Thrombotic thrombocytopenic purpura and hemolytic uremic syndrome are distinct pathologic entities. A review of 56 autopsy cases. Arch Pathol Lab Med 2003 Jul;127(7):834-9.

(2) Loirat C, Noris M, Fremeaux-Bacchi V. Complement and the atypical hemolytic uremic syndrome in children. Pediatr Nephrol. 2008 Nov;23(11):1957-72.

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net product sales	$ 141,569	$ 102,628	$ 384,982	$ 276,151
Cost of sales (1)	16,495	11,895	44,215	32,167
Operating expenses:				
Research and development (1)	25,153	21,323	71,217	58,700
Selling, general and administrative (1)	57,208	41,523	163,941	120,880
Total operating expenses	82,361	62,846	235,158	179,580
Operating income	42,713	27,887	105,609	64,404

Other expense	(106)	(205)	(845)	(289)
Debt exchange expense	-	-	-	(3,395)
Income before income taxes	42,607	27,682	104,764	60,720
Income tax provision	14,734	951	34,184	2,681
Net income	$ 27,873	$ 26,731	$ 70,580	$ 58,039
Earnings per common share				
Basic	$ 0.31	$ 0.31	$ 0.79	$ 0.69
Diluted	$ 0.30	$ 0.29	$ 0.76	$ 0.65
Shares used in computing earnings per common share				
Basic	89,490	87,447	89,003	84,464
Diluted	93,021	90,946	92,580	90,246

(1) The following is the share-based compensation expense included in the respective captions of the condensed consolidated statements of operations above:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Share-based compensation expense:				
Cost of sales	$ 290	$ -	$ 855	$ -
Research and development	2,029	2,108	6,139	6,163
Selling, general and administrative	6,060	4,871	17,739	15,690
	$ 8,379	$ 6,979	$ 24,733	$ 21,853

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30, 2010	December 31, 2009
Cash, cash equivalents and marketable securities	$ 298,554	$ 176,220
Trade accounts receivable, net	154,088	113,731
Inventories, net	60,412	40,885
Deferred tax assets, current	19,265	16,726
Other current assets	25,469	25,894
Property, plant and equipment, net	162,111	164,691
Deferred tax assets, noncurrent	164,446	194,308
Other noncurrent assets	57,463	53,946
Total assets	$ 941,808	$ 786,401
Accounts payable and accrued expenses	$ 101,521	$ 83,187
Other current liabilities	15,693	2,075
Long term debt	3,718	9,918
Other noncurrent liabilities	9,060	2,865
Total liabilities	129,992	98,045
Total stockholders' equity	811,816	688,356
Total liabilities and stockholders' equity	$ 941,808	$ 786,401

SOURCE: Alexion Pharmaceuticals, Inc.

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